

CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

**INITIAL STATEMENT OF REASONS FOR THE
PROPOSED ADOPTION OF WORKING GROUP
CONFLICT OF INTEREST REGULATIONS**

HEARING DATE: None scheduled.

SUBJECT MATTER OF PROPOSED REGULATIONS: Conflict of Interest Regulations for CIRM Working Groups

SECTIONS AFFECTED: The proposed regulations adopt Chapter 1 and sections 100001, 100002, 100003 and 100004 of Title 17 of the California Code of Regulations

SPECIFIC PURPOSE AND FACTUAL BASIS FOR EACH ADOPTION:

SECTION 100001 – DEFINITIONS:

Purpose:

The following definitions shall apply to language contained in Sections 100001 through 100004 of these regulations.

(a). “Applicant.” This term defines who an applicant is for purposes of determining the scope of disclosure and potential disqualification of working group members. Pursuant to Health and Safety Code section 125292.10, subdivision (j), defining “grantee,” the term “applicant” distinguishes each campus of a statewide university from each other. The term includes investigators, project directors and the applicant entity – those with significant oversight and association with the application and applicant entity.

(b). “CIRM.” This acronym stands for the agency created by Proposition 71, adopted by the voters in November, 2004, the California Institute for Regenerative Medicine. This is the agency that has oversight and implementation authority for Proposition 71.

(c). “Facilities Working Group.” This refers to the Scientific and Medical Facilities Working Group, one of three working groups created by Proposition 71 to advise the Independent Citizen’s Oversight Committee (“ICOC”), the governing body of the CIRM, the members of which are subject to these regulations.

(d). “Grant.” This term is defined by Health and Safety Code section 125292.10, subdivision (i), to mean a grant, loan or guarantee. This term is included in these regulations for ease of reference.

(e). “Grantee.” This term tracks the definition contained in Health and Safety Code section 125292, subdivision (j), to mean the recipient of a grantee from the institute.

Each campus of a statewide university shall be considered as a separate and individual grantee institution. This term is included in these regulations for ease of reference.

(f). “Grants Review Working Group.” This refers to the Scientific and Medical Research Funding Working Group, one of three working groups created by Proposition 71 to advise the ICOC, the members of which are subject to these regulations.

(g). “Member.” Because ICOC members who also serve on working groups are already subject to the Political Reform Act’s disclosure and disqualification rules, the provisions of the working group conflict regulations apply only to the remaining members of the working groups. Thus, the term “member” is defined to include only non-ICOC individuals appointed to serve as voting members on a working group.

(h). “Principal Investigator.” Principal investigators play key roles in the creation and administration of a grant application on behalf of the investigator and the applicant institution. As such, these individuals are identified in conflict of interest regulations as a potential source of conflict for working group members. This definition clarifies the term to mean an individual designated by the grantee to direct the project or activity being supported by the grant.

(i). “Project Director.” A project director is term used by some institutions to direct the project or activity being funded by the grant. As with a “principal investigator,” such individuals have an important function in the grant process and thus must be identified as potential sources for conflicts of interest. The term means an individual designated by the grantee to direct the project or activity being supported by the grant.

(j). “Standards Working Group.” This refers to the Scientific and Medical Accountability Standards Working Group, one of three working groups created by Proposition 71 to advise the ICOC, the members of which are subject to these regulations.

(k). “Working Group.” This term refers generally to any of the three advisory bodies to the ICOC and to which these regulations apply.

Rationale:

To make specific the language and terminology used in formulating regulations.

SECTION 100002 – CONFLICTS OF INTEREST – SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS WORKING GROUP.

Purpose:

To ensure that working group members do not participate in decisions in which they have a conflict of interest, this regulation describes the disclosure and disqualification rules applicable to members of the Standards Working Group.

Subdivision (a) states the general rule that members are prohibited from deriving direct financial benefit from CIRM grants and from acting as a Principal Investigator on any CIRM-funded grant. Senior academic officers who oversee and advise researchers in their institution or who sign off on grants, loans or contracts shall not be deemed to have a conflict of interest.

Subdivision (b) describes the financial interests of members that must be disclosed and requires the member certify under penalty of perjury that the pertinent information has been disclosed. The member must disclose real property, biotechnology and pharmaceutical holdings, and certain academic or non-profit research interests above a threshold value of \$5,000 held by the member or individuals with whom the member is affiliated in a certain fashion.

In addition to disclosure the regulation provides in **subdivision (c)** for disqualification of the member from participating in certain decisions of the working group. This provision states that a conflict of interest exists when there is a financial or other interest that significantly impairs the member's objectivity or that creates an unfair advantage for any person, institution or company with whom the member is affiliated. Thus, any financial interest disclosed pursuant to subdivision (b) of the regulation will result in a conflict of interest if that interest is the subject of a decision of the working group. This subdivision allows the President of CIRM to allow a member who otherwise has a conflict of interest to participate in the *discussion* of a grant (but *not vote*) where the special expertise of a member is found to outweigh any possible bias. In these circumstances the CIRM staff will publicly disclose the working group member's interest before the meeting.

Subdivision (d) requires the voting, disclosure and participation records of the working group be preserved for audit purposes and requires the CIRM or auditor to report violations of these rules to the Legislature and describe the CIRM's corrective actions.

Rationale:

This regulation is necessary to ensure the success of the CIRM research program and its ability to maintain the confidence of the people of California, which depends critically upon the agency's ability to fund the highest quality research proposals, chosen without bias. Strong CIRM conflict of interest policies are thus essential.

The proposed regulation for the Standards Working Group members describes several types of conflicts of interest and requires members to identify and describe in detail the source of any conflict of interest that corresponds to the identified types. If a conflict of interest is identified, the CIRM is responsible for ensuring that the member does not participate in discussing or voting to recommend policies that would present a conflict of interest.

Based on input from the public, the draft regulation in subdivision (a) prohibits members from deriving direct financial benefit from the CIRM through grants, loans or contracts.

This is necessary to ensure the decisions of members are free from the appearance of bias in the decision-making process. The second sentence clarifies that senior academic officers, whose oversight is farther removed than that of a Principal Investigator, is not deemed to have a conflict of interest by virtue of that position. This clarification is a common-sense recognition of the lack of personal direct financial benefit likely to inure to senior academic officers.

The groups identified in subdivision (b) of the regulation are targeted as the most logical sources from which a conflict of interest likely would arise. Accordingly, these entities are required to be disclosed under penalty of perjury, which will ensure the diligence of the disclosures. The disclosure under penalty of perjury is consistent with existing requirements of individuals who file a Statement of Economic Interests pursuant to the Government Code.

Just as the Political Reform Act contains separate disclosure and disqualification requirements, proposed subdivision (c) defines the circumstances under which a working member is required to disqualify himself or herself from the decision-making process of the working group. Because of the unique and highly specialized expertise required in order to inform and advise the ICOC in its adoption of the proper medical and ethical standards, the President may, in exceptional cases, allow an otherwise ineligible member to participate in the discussion only of a particular matter, but *not* vote. This provision can be analogized to the allowance under the Political Reform Act for public officials with a conflict of interest to nevertheless participate in the process as a member of the public would under certain circumstances. By publicly disclosing the working group members' interests before the meeting one ensures that the public is informed of the particular member's participation and allows for public monitoring of the circumstances surrounding the use of the exception.

Health and Safety Code section 125290.50, subdivision (f), exempts most working group records from disclosure. Nevertheless, subdivision (d) of the regulation requires that confidential disclosure documents would be maintained to ensure that auditors would be able to confirm that working group members have complied with the conflict of interest provisions applicable to them by virtue of these regulations. The regulation goes beyond typical provisions of the Political Reform Act and requires the CIRM to notify the Legislature in the unlikely event the rules are violated and requires a review of corrective actions taken by CIRM to ensure compliance in the future. This ensures that the Standards Working Group will have the strictest ethical guidelines of any state advisory group otherwise exempt from the Political Reform Act.

SECTION 100003. CONFLICTS OF INTEREST – NON-ICOC MEMBERS OF THE SCIENTIFIC AND MEDICAL RESEARCH OF FUNDING WORKING GROUP.

Purpose:

To ensure that working group members do not participate in decisions in which they have a conflict of interest, this regulation describes the disclosure and disqualification rules applicable to members of the Grants Review Working Group.

Subdivision (a) contains the prohibition against participating in a decision of the working group in which the member has a conflict. The second sentence elaborates on the circumstances that may comprise a conflict of interest, identifying three types of interests – financial, professional and personal.

Subdivision (b) defines what constitutes a “financial interest” that gives rise to a conflict of interest for a working group member. The four types of interests are self-explanatory and are the logical and most likely sources for a potential conflict of interest.

Subdivision (c) defines what constitutes a “professional” conflict of interest. The three circumstances identified therein are self-explanatory and are the logical and most likely sources for a potential conflict of interest.

Subdivision (d) defines what constitutes a “personal” conflict of interest. The two circumstances identified therein are self-explanatory and are the logical and most likely sources for a potential conflict of interest.

Subdivision (e) requires working group members to disclose confidentially and under penalty of perjury the financial interests enumerated therein. The subparts require disclosure of academic, non-profit, biotechnology, pharmaceutical and real property interests above a certain threshold held by the member and his or her spouses and anyone else with whom the member shares a common financial interest.

Subdivision (f) requires each non-ICOC member to report to CIRM staff any conflict of interest that may arise, including those identified in subdivisions (b) through (d) of the regulation. The regulation requires a member under these circumstances to leave the room when the particular application in question is discussed. The member is prohibited from participating in any manner in either the discussion or the vote on the matter. Because of the unique and highly specialized expertise required in order to inform and advise the ICOC in its decisions regarding which grants to fund, the President may, in exceptional cases, allow an otherwise ineligible member to participate in the discussion only of a particular matter, but *not* vote. This provision can be analogized to the allowance under the Political Reform Act for public officials with a conflict of interest to nevertheless participate in the process as a member of the public would under certain circumstances. By publicly disclosing the working group members’ interests before the meeting one ensures that the public is informed of the particular member’s participation and allows for public monitoring of the circumstances surrounding the use of the exception.

Subdivision (g) requires each non-ICOC member to sign a pre-review statement indicating any possible conflicts of interest the person may have and must also sign a post-review statement that they did not participate in the review of any application for

which they might have had a conflict of interest. Where the member's participation in the discussion *only* by virtue of permission granted by the President, that information will be disclosed on the post-review form.

Subdivision (h) requires the voting, disclosure and participation records of the working group be preserved for audit purposes and requires the CIRM or auditor to report violations of these rules to the Legislature and describe the CIRM's corrective actions.

Rationale:

This regulation is necessary to ensure the success of the CIRM research program and its ability to maintain the confidence of the people of California, which depends critically upon the agency's ability to fund the highest quality research proposals, chosen without bias. Strong CIRM conflict of interest policies are thus essential.

Subdivision (a) provides the necessary rule prohibiting participation by working group members who have a conflict of interest in an applicant before the working group. Unlike the Political Reform Act, which focuses its ethics provisions solely at financial interests, this subdivision broadens the scope of the regulation to include professional and personal circumstances that may give rise to a conflict of interest.

Subdivision (b)'s specificity in defining the term "financial" conflict of interest is necessary to provide clear guidance as to the scope of interests intended to be covered by the regulation. These interests are common-sense and logical sources of potential conflicts of interests for members of the Grants Working Group. The interests identified take into account the context of research grants. As a result, the term includes interests as a result of a member's (or spouse's) employment with the grantee institution or status as its principal investigator, is under consideration for a faculty position with the applicant institution, if there is *any* potential for receiving any financial benefit from the grantee institution, or indirect benefit of more than \$5,000.

Subdivisions (c) and (d) are necessary to give specificity to the terms "professional" and "personal" conflicts of interest and give clear guidance as to the scope of interests subject to the regulation's prohibition.

The groups identified in subdivision (e) of the regulation are targeted as the most logical sources from which a conflict of interest likely would arise. Accordingly, these entities are required to be disclosed under penalty of perjury, which will ensure the diligence of the disclosures. The disclosure under penalty of perjury is consistent with existing requirements of individuals who file a Statement of Economic Interests pursuant to the Government Code.

Just as the Political Reform Act contains separate disclosure and disqualification requirements, proposed subdivision (f) defines the circumstances under which a working member is required to disqualify himself or herself from the decision-making process of the working group. Because of the unique and highly specialized expertise required in

order to inform and advise the ICOC in its determination of what grants to fund, the President may, in exceptional cases, allow an otherwise ineligible member to participate in the discussion only of a particular matter, but *not* vote. This provision can be analogized to the allowance under the Political Reform Act for public officials with a conflict of interest to nevertheless participate in the process as a member of the public would under certain circumstances. By publicly disclosing the working group members' interests before the meeting one ensures that the public is informed of the particular member's participation and allows for public monitoring of the circumstances surrounding the use of the exception.

Subdivision (g)'s provisions for pre- and post-review certification demonstrate the vigilance CIRM staff and working group members will maintain to ensure bias-free decision-making with regard to the research grant recommendations. By examining before each grant session all of the potential sources of conflicts of interest, the members are assured being best able to identify grant applications for which the member may have a conflict of interest. The assurance under penalty of perjury further assures that all pre- and post-reviews will be done with the utmost diligence.

Health and Safety Code section 125290.50, subdivision (f), exempts most working group records from disclosure. Nevertheless, subdivision (h) of the regulation requires that confidential disclosure documents would be maintained to ensure that auditors would be able to confirm that working group members have complied with the conflict of interest provisions applicable to them by virtue of these regulations. The regulation goes beyond typical provisions of the Political Reform Act and requires the CIRM to notify the Legislature in the unlikely event the rules are violated and requires a review of corrective actions taken by CIRM to ensure compliance in the future. This ensures that the Standards Working Group will have the strictest ethical guidelines of any state advisory group otherwise exempt from the Political Reform Act.

SECTION 100004. CONFLICTS OF INTEREST – NON-ICOC MEMBERS OF THE SCIENTIFIC AND MEDICAL FACILITIES WORKING GROUP.

Purpose:

To ensure that working group members do not participate in decisions in which they have a conflict of interest, this regulation describes the disclosure and disqualification rules applicable to members of the Facilities Working Group.

Subdivision (a) contains the prohibition against participating in a decision of the working group in which the member has a conflict. The second sentence prohibits non-ICOC members from receiving compensation from any construction or development entity providing services for medical research facilities. The last sentence bars non-ICOC members from providing certain brokerage services for any grant applicant and bars the member from being a recipient of a CIRM-funded grant.

Subdivision (b) elaborates on the circumstances that may comprise a conflict of interest, identifying two types of interests – financial and professional.

Subdivision (c) defines what constitutes a “financial interest” that gives rise to a conflict of interest for a working group member. The four types of interests are self-explanatory and are the logical and most likely sources for a potential conflict of interest.

Subdivision (d) defines a “professional” conflict of interest as arising when the member and the project director or manager of an application are or plan to be engaged in a joint project.

Subdivision (e) requires working group members to disclose confidentially and under penalty of perjury the financial interests enumerated therein. The subparts require disclosure of academic, non-profit, real property, and real estate development interests above a certain threshold held by the member or his or her spouses and anyone else with whom the member shares a common financial interest.

Subdivision (f) requires each non-ICOC member to report to CIRM staff any conflict of interest that may arise, including those identified in subdivisions (b) through (d) of the regulation. The regulation requires a member under these circumstances to leave the room when the particular application in question is discussed. The member is prohibited from participating in any manner in either the discussion or the vote on the matter. Because of the unique and highly specialized expertise required in order to inform and advise the ICOC in its decisions regarding which grants to fund, the President may, in exceptional cases, allow an otherwise ineligible member to participate in the discussion only of a particular matter, but *not* vote. This provision can be analogized to the allowance under the Political Reform Act for public officials with a conflict of interest to nevertheless participate in the process as a member of the public would under certain circumstances. By publicly disclosing the working group members’ interests before the meeting one ensures that the public is informed of the particular member’s participation and allows for public monitoring of the circumstances surrounding the use of the exception.

Subdivision (g) requires each non-ICOC member to sign a pre-review statement indicating any possible conflicts of interest the person may have and must also sign a post-review statement that they did not participate in the review of any application for which they might have had a conflict of interest. Where the member’s participation in the discussion *only* by virtue of permission granted by the President, that information will be disclosed on the post-review form.

Subdivision (h) requires the voting, disclosure and participation records of the working group be preserved for audit purposes and requires the CIRM or auditor to report violations of these rules to the Legislature and describe the CIRM’s corrective actions. The proposed regulations identify three kinds of conflicts of interest: financial, professional and personal and in each case define the types of conflicts that are possible. At the time of appointment to the Working Group, all reviewers and patient advocate

members are asked to sign a statement that asserts that they have read and understand the CIRM policy.

Rationale:

This regulation is necessary to ensure the success of the CIRM research program and its ability to maintain the confidence of the people of California, which depends critically upon the agency's ability to fund the highest quality research proposals, chosen without bias. Strong CIRM conflict of interest policies are thus essential.

Subdivision (a) provides the necessary rule prohibiting participation by working group members who have a conflict of interest in an applicant before the working group. Moreover, given the context of facilities grants, the regulation provides further protection by barring non-ICOC members from employment with any construction or development entity that provides services for medical research facilities. The additional provisions regarding brokerage services and receipt of compensation from recipients of grants are common-sense provisions that add a necessary layer of protection to prevent the most obvious potential sources of conflicts.

Subdivision (b): This provision states the prohibition against participating in decisions with which a member has a conflict of interest. Unlike the Political Reform Act, which focuses its ethics provisions solely at financial interests, this subdivision broadens the scope of the regulation to include professional and personal circumstances that may give rise to a conflict of interest.

Subdivision (c)'s specificity in defining the term "financial" conflict of interest is necessary to provide clear guidance as to the scope of interests intended to be covered by the regulation. These interests are common-sense and logical sources of potential conflicts of interests for members of the Facilities Working Group. The interests identified take into account the context of facilities grants. As a result, the term includes interests as a result of a member's (or spouse's) employment with any real estate or development entity that is identified on an application, potential employment with an entity, and any direct or indirect financial benefit.

Subdivision (d) is necessary to give specificity to the term "professional" conflict of interest and give clear guidance as to the scope of interests subject to the regulation's prohibition.

The groups identified in subdivision (e) of the regulation are targeted as the most logical sources from which a conflict of interest likely would arise. Accordingly, these entities are required to be disclosed under penalty of perjury, which will ensure the diligence of the disclosures. The disclosure under penalty of perjury is consistent with existing requirements of individuals who file a Statement of Economic Interests pursuant to the Government Code.

Just as the Political Reform Act contains separate disclosure and disqualification requirements, proposed subdivision (f) defines the circumstances under which a working member is required to disqualify himself or herself from the decision-making process of the working group. Because of the unique and highly specialized expertise required in order to inform and advise the ICOC in its determination of what grants to fund, the President may, in exceptional cases, allow an otherwise ineligible member to participate in the discussion only of a particular matter, but *not* vote. This provision can be analogized to the allowance under the Political Reform Act for public officials with a conflict of interest to nevertheless participate in the process as a member of the public would under certain circumstances. By publicly disclosing the working group members' interests before the meeting one ensures that the public is informed of the particular member's participation and allows for public monitoring of the circumstances surrounding the use of the exception.

Subdivision (g)'s provisions for pre- and post-review certification demonstrate the vigilance CIRM staff and working group members will maintain to ensure bias-free decision-making with regard to the facilities grant recommendations. By examining before each grant session all of the potential sources of conflicts of interest, the members are assured being best able to identify grant applications for which the member may have a conflict of interest. The assurance under penalty of perjury further assures that all pre- and post-reviews will be done with the utmost diligence.

Health and Safety Code section 125290.50, subdivision (f), exempts most working group records from disclosure. Nevertheless, subdivision (h) of the regulation requires that confidential disclosure documents would be maintained to ensure that auditors would be able to confirm that working group members have complied with the conflict of interest provisions applicable to them by virtue of these regulations. The regulation goes beyond typical provisions of the Political Reform Act and requires the CIRM to notify the Legislature in the unlikely event the rules are violated and requires a review of corrective actions taken by CIRM to ensure compliance in the future. This ensures that the Standards Working Group will have the strictest ethical guidelines of any state advisory group otherwise exempt from the Political Reform Act.